

November 30, 2000

Reo Menning
Deputy Director
Silicones Environmental, Health and Safety Council
11921 Freedom Drive Suite 550
Reston, VA 20190

Dear Ms. Menning:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for 3-(2,3-epoxypropoxy)propyltrimethoxysilane (TMSPGE; CAS # 2530-83-8), submitted July 20, 2000. I commend the Silicones Environmental, Health and Safety Council for their commitment to the HPV Challenge Program and encourage you to take appropriate steps to make your submission a successful contribution.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Chemical RTK HPV Challenge Program website EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

As explained in the enclosed comments, SEHSC needs to articulate support for its conclusion that a screening level characterization of TMSPGE is feasible without reproductive toxicity data. The arguments SEHSC outlines in its proposal need to be strengthened by providing better documentation and incorporation of a discussion of structure-activity relationships for the reproductive effects of siloxanes.

In the event that a reproductive test is necessary, I would like to point out that this submission is for an individual chemical, and as stated in the October 14, 1999 letter to sponsors (<http://www.epa.gov/chemrtk/ceoltr2.htm>), animal testing for SIDS endpoints for individual chemicals shall be deferred until November, 2001.

SEHSC also needs to supply better support for its conclusion that the submitted ecological data are adequate. The ecotoxicity robust summaries contain insufficient information to permit an assessment of data adequacy. SEHSC needs to supply more information about the existing studies, if available, and reevaluate testing needs in light of their adequacy.

As with other submissions where the available data are either inadequate or insufficiently documented, this case will remain open until adequate documentation is in hand.

EPA will post this letter and the attached Comments on the Chemical RTK web site within the next few days. As noted in the comments, we ask that SEHSC advise the Agency, within 60 days of the posting on the Chemical RTK website, of any modifications to its submission.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-260-3470. Submit general questions about the HPV Challenge Program through the Chemical RTK web site comment button or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsc hotline@epa.gov.

I thank you for your submissions and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/s/

Oscar Hernandez, Director
Risk Assessment Division

Attachment

cc: W. Sanders
C. Auer
N. Patel
A. Abramson